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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/717,057 | 11/21/2000 | Michael Brines | 10165-010-999 | 5119 |

7590

04/05/2004

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| EXAMINER |
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DEBERRY, REGINA M

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| ART UNIT | PAPER NUMBER |
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1647

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------|--------------------------------------|--------------------------------------|--|
| Advisory Action | Application No. 09/717,057 | Applicant(s) BRINES ET AL. | |
| | Examiner Regina M. DeBerry | Art Unit 1647 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 16 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 2-7 and 9.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The provisional rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/547,220 as set forth at pages 7-8 of the Office Action (01 November 2002) is withdrawn in view of the amendment (16 January 2004).

The provisional rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/717,053 as set forth at pages 8-9 of the Office Action (01 November 2002) is withdrawn in view of the amendment (18 January 2004).

The provisional rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/716,960 as set forth at pages 9-10 of the Office Action (01 November 2002) is withdrawn in view of the amendment (18 January 2004).

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-7 and 9 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for enhancing the function of normal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO, wherein said enhancing the function of excitable tissue results in the enhancement of associative learning or memory does not reasonably provide enablement for a method for enhancing the function of abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO, wherein said enhancing the function of excitable tissue results in the enhancement of associative learning. The rejection is maintained for reasons of record.

Applicants state that the Examiner indicated that the data presented in Exhibit D, (submitted by Applicants on May 1, 2003 hereinafter referred to as Exhibit D"), which contained a compilation of data presented as examples in Applicants' copending application, would obviate the instant rejection if the information in Exhibit D were properly submitted, i.e., submitted under oath by Applicants. In response, Applicants identify the copending application as U.S. Patent Application No.: 10/188,905 which published as Patent Application Publication No.: US 2003/0072737, a copy of which is submitted herewith as Exhibit A. Applicants state that the Examiner is invited to Example 9 at page 27 therein, which is identical in content to the information previously submitted as Exhibit D. Example 9 teaches the ability of erythropoietin to restore diminished cognitive function in mice after receiving brain trauma as described in Brines et al. PNAS 2000, 97:10295-10672.

Applicants argument have been fully considered but are not deemed persuasive. On page 7-8 of Applicants arguments and remarks (Amendment filed 01 May 2003), Applicants stated that Exhibit D is a compilation of data presented as examples in Applicants copending applications which utilize the teachings provided in the instant specification to corroborate the method for enhancing learning and memory in mammals with abnormal excitable tissue by peripherally administering EPO. The Examiner did not consider Exhibit D because it was not properly submitted. The Examiner stated if Exhibit D was properly submitted, it would obviate the rejection. The Examiner made this statement based on Applicants assertion that Exhibit D would corroborate the method for enhancing learning and memory in mammals with abnormal excitable tissue. The Examiner has now considered Exhibit D based on Applicants disclosure of the copending published application. The animal model in Example 9 of Patent Application Publication US 2003/0072737 A1 (page 27) would only correlate to abnormal tissue due to injury. The animal model in Example 9 does not fairly correlate to the scope of the instant claims. The instant claims would encompass conditions such as stroke, Alzheimers disease perhaps even mental retardation, as mammals with these conditions would have abnormal excitable tissue and diminished learning or memory. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.


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